

### III. REMARKS

#### Preliminary Remarks

Upon entry of this Amendment, claims 12 to 14 and 16 to 20, 22 to 25, 27, and 28 will be pending, of which claims 12, 18, 24, and 27 are independent. Claims 12, 18, 24, and 27 are amended to incorporate the limitations of claims 15, 21, 26, and 29 respectively, which are canceled. Claim 27 is also amended to be directed to, *inter alia*, a method for preventing mortality or sudden death caused by the reoccurrence of myocardial infarction. Support for the claim amendments can be found in the specification as filed (see, for example, page 2, lines 11 to 15).

The specification is amended to incorporate the priority information, which has been previously been acknowledged by the United States Patent and Trademark Office (see filing receipt and official action dated November 22, 2002). The applicants believe that no new matter is introduced as a result of these amendments.

This response is filed under 37 C.F.R. §1.114 along with a request for continued examination (RCE), a petition for a three-month extension of time, and the required fees. The applicants respectfully request reconsideration and allowance of the present application.

#### Patentability Remarks

##### *Rejection under 35 U.S.C. §112 –*

Claims 27 to 29 were rejected under 35 U.S.C. §112, first paragraph, as not being enabled for preventing mortality or sudden death in general. This rejection is rendered moot in view of the amendments to the claims.

Claim 29 is canceled and claims 27 and 28 are amended to, *inter alia*, a method for preventing mortality or sudden death caused by the reoccurrence of myocardial infarction. The examiner admits that the specification provides enablement for a method for preventing mortality or sudden death caused by the reoccurrence of myocardial infarction. Therefore, the applicants respectfully request withdrawal of this rejection.

*Rejection under 35 U.S.C. §103 –*

Claims 12 to 29 were rejected under 35 U.S.C. §103(a) as being anticipated by Leaf *et al.* (U.S. Pat. No. 5,760,081) in view of JP 4029928 (to Nippon Oils & Fats Co. Ltd., Derwent Abstract 1992-085863). The applicants respectfully traverse in view of the preceding amendments and succeeding remarks.

Claims 15, 21, 26, and 29 are canceled. Claims 12 to 14 and 16 to 20, 22 to 25, 27, and 28 are amended to, *inter alia*, a method comprising administering a therapeutically effective amount of a medicament, wherein the medicament is administered orally. In contrast, Leaf *et al.* describe prevention of imminent ventricular fibrillation. They define imminent ventricular fibrillation as “an emergency situation in which the patient may proceed from a medical condition involving the heart, e.g., heart attack symptoms, to subsequent ventricular fibrillation and cardiac arrest at any moment” (column 2, lines 42 to 46, emphasis added).

The examiner uses JP 4029928 to disclose oral bioavailability of the fatty acid ester. A patient undergoing imminent ventricular fibrillation, as in Leaf *et al.*, would not be administered an oral formulation, which takes time to be effective. Indeed, Leaf *et al.* describe methods such as direct injection into the heart or an artery of the heart, and intravenous injection (column 1, lines 50 to 54), *i.e.*, all immediate treatments. Leaf *et al.* provide no motivation to modify their invention to a method of oral administration.

Furthermore, considering the criticality of the medical situation of the patients in Leaf *et al.* (*i.e.*, imminent ventricular fibrillation), one of ordinary skill in the art would not administer to these patients a (relatively) slow-acting form, such as an oral dose. Such a patient might expire of a cardiac arrest before the formulation dissolves, enters the blood stream and makes its way to the appropriate parts of the body. Thus, not only do Leaf *et al.* teach away from the present invention, but the combination of Leaf *et al.* and JP 4029928 does not provide a reasonable expectation of success.

The applicants respectfully submit that claims 12 to 14 and 16 to 20, 22 to 25, 27, and 28 are not anticipated by Leaf *et al.* in view of JP 4029928 and respectfully request withdrawal of this rejection.

### III. CONCLUSION

In view of the amendments and remarks above, the applicant respectfully submits that this application is in condition for allowance and request favorable action thereon.

In the event this paper is not timely filed, the applicant hereby petitions for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300, along with any other additional fees which may be required with respect to this paper, referencing Attorney Docket No.101615-00012.

Respectfully submitted,

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